Remarks

This Amendment filed in response to the Office Action dated June 30, 2004, accompanied by an extension of time for two additional month is timely filed within the five month time period for response, which time period is set to expire on November 30, 2004. Reconsideration of this application is requested in view of the foregoing amendments and the following remarks.

Reconsideration of the application is requested in view of the following remarks. The Applicants acknowledge with appreciation that the Examiner has accepted the Terminal Disclaimer filed on March 31, 2004.

Status of Claims 32-37

The Examiner stated that claims 1-31 were pending in the above referenced application. However, claims 1-37 were originally filed and were acknowledged pending as of the Office Action dated January 15, 2004. Applicant cannot find any place where claims 32 to 37 were cancelled, deleted or otherwise withdrawn from consideration. Thus, claims 32 to 37 should be pending. The only rejection pertaining to claims 32 to 37 was obviated by a terminal disclaimer. Thus, applicant respectfully suggest that claims 32-37 are allowable. Clarification of the record is duly requested.

Claim Rejections – 35 USC §103

Claims 1-31 were rejected under 35 U.S.C. 103(a) as being unpatentable over Smith et al (US 5,378,475) in view of Yaacobi (US 6,413,540). Applicant respectfully traverses this rejection and requests reconsideration.

The claims of the present invention cover sustained release drug delivery devices, methods of use and methods of manufacture. Claims 1 to 23 cover a drug delivery device. Claims 24 to 31 cover a method of using a drug delivery device.

Claims 1-23

In claim 1, the device comprises a drug core comprising a therapeutically effective amount of at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect. There is also a unitary cup essentially that is impermeable to the passage of the agent that surrounds and defines an internal

compartment to accept the drug core. The unitary cup comprises an open top end with at least one recessed groove around at least some portion of the open top end of the unitary cup. The device also comprises a prefabricated plug, which is permeable to the passage of the agent. The prefabricated plug is positioned at the open top end of the unitary cup wherein the groove interacts with the prefabricated plug holding the prefabricated plug in position and closing the open top end. The permeable plug allows passage of the agent out of the drug core, through the permeable plug, and out the open top end of the unitary cup. Claims 2-11 depend from claim 1 and contain all of the elements of claim 1.

Claim 12 of the invention is likewise a sustained release drug delivery device. The drug delivery device comprises a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect. The device describes a unitary cup essentially impermeable to the passage of the agent that surrounds and defines an internal compartment to accept said drug core. The unitary cup comprising an open top end and at least one lip around at least a portion of said open top end of the unitary cup. A prefabricated plug that is permeable to the passage of the agent is positioned at the open top end of the unitary cup where the lip interacts with the prefabricated plug holding the prefabricated plug in position and closing the open top end of the permeable plug. Claims 13-23 depend from claim 12 and contain all of the elements of claim 12.

In claim 1, a prefabricated plug is held in place by a recessed groove. The prefabricated plug is in a position closing the open top end. In claim 12, a prefabricated plug is held in place by a lip. The prefabricated plug is in a position closing the open top end. The permeable plug allows passage of the agent out of the drug core through the permeable plug. Because the device is assembled with a prefabricated plug, the prefabricated plug can be manufactured separate from the manufacture of the agent and drug core. While it is generally desirable to minimize the handling of an agent during the processing steps, some processing steps can subject an agent to conditions that would cause chemical degradation of the aged. A prefabricated plug that requires heat curing, such as poly(vinyl alcohol), can be manufactured separately from the agent. Therefore, the agent does not have to be subject to thermal curing with the prefabricated plug.

U.S Patent No. 5,378,475 ("Smith") teaches a drug delivery device that is assembled in layers. A first layer is a permeable coating 30 that surrounds the drug delivery device. The

second layer is an impermeable coating 10 and optionally 20. A third layer is a permeable coating. The coatings mean that the drug core is processed through all of the steps of manufacture. The multiple handling of the drug core during processing of the Smith device is avoided in the present invention because the present invention uses a prefabricated plug that is fabricated before assembly of the device.

U.S. Patent No. 6, 413,540 ("Yaacobi") does not have a prefabricated plug at all. It teaches placement of a tablet in a well. A retaining member holds the tablet in place. However, there is no prefabricated plug closing the open top end of the drug delivery device as set forth in claim 1 and claim 12. Thus, neither Smith nor Yaacobi teach all of the elements of claims 1 and 12. Accordingly, a prima facie case of obviousness has not been met.

Furthermore, a device cannot be made by the combined teaching of Smith and Yaacobi where the drug passes through a prefabricated plug. Thus, the result of avoiding unnecessary handling of the drug core during the processing step is new to the present invention. Thus, the present invention has unexpected benefits in view of a prior art device based upon the combined techniques of both prior art references.

Method of Use Claims 24-31

Claim 24 discloses a method of providing controlled and sustained administration of an agent effective in obtaining a desired local or systemic physiological or pharmacological effect. The method comprises inserting a sustained release drug delivery device including a drug core having a therapeutically effective amount of at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect. The device further has a unitary cup that is essentially impermeable to the passage of the agent that surrounds and defines an internal compartment to accept the drug core. The unitary cup comprises an open top end with at least one recessed groove around at least some portion of the open top end of the unitary cup. The device also has a prefabricated plug which is permeable to the passage of the agent positioned at the open top end of the unitary cup wherein the groove interacts with the prefabricated permeable plug holding the prefabricated permeable plug in position and closing the open top end. The permeable plug allows passage of the agent out of the drug core, through the permeable plug, and out of the open top end of the unitary cup. Claims 25-27 depend from claim 24 and contain all of the elements of claim 24.

Claim 28 represents a method for providing controlled and sustained administration of an agent effective in obtaining a desired local or systemic physiological or pharmacological effect. According to the method, a sustained release drug delivery device is inserted at a desired location in the body of a mammalian organism. The sustained release drug delivery device comprises a drug core comprising at least one agent effective in obtaining a diagnostic effect or effective in obtaining a desired local or systemic physiological or pharmacological effect. The device further includes a unitary cup essentially impermeable to the passage of the agent that surrounds and defines an internal compartment to accept said drug core. The unitary cup comprising an open top end and at least one lip around at least a portion of said open top end of the unitary cup. A prefabricated plug permeable to the passage of the agent is positioned at said open top end of the unitary cup wherein the lip interacts with the prefabricated plug holding the prefabricated plug in position and closing said open top end of the unitary cup. The permeable plug allows passage of the agent out of the drug core, through the permeable plug, and out the open top end of the unitary cup.

Due to the similarities between the device claimed in claims 1 and 2 and the device provided in claims 24 and 28, Applicant incorporates all of the arguments, pertaining to the patentability of claims 1 and 12 into the argument relating to the method of use claims 24 and 28.

Additionally, both the method of claim 24 and the method of claim 28 include the step inserting a drug delivery device that has a prefabricated plug that is permeable to the passage of the agent. The prefabricated plug is positioned at the open top end and closes the open top end of the unitary cup.

Nowhere in Smith or Yaacobi does it mention providing a drug delivery device that has a prefabricated plug that is described above. Thus, the Examiner has not met the burden of proof regarding these method claims. Furthermore, neither Smith nor Yaacobi teach the method of providing controlled and sustained release of an agent that has the benefits of the claimed invention as set forth above. Applicant asserts that claims 24 and 28 and the claims that depend from these claims are not obvious and are patentable. Reconsideration is respectfully requested.

In view of the foregoing arguments, Applicant believes that the application is in condition for allowance. An early and favorable action on the merits is solicited.

Respectfully submitted,

Dated: November 24, 2004

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